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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,141	06/23/2003	Aaron K. Sato	10280-058001	7569
26161	7590	01/27/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/602,141	Applicant(s) SATO ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 45-63 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,15-40 and 45-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-8 and 11-12) is acknowledged. The traversal is on the grounds that each of Groups II-IV depends from claim 1. Restriction is only appropriate if the inventions are independent or distinct. It is traversed because according to MPEP 802.01, independent, means not dependent. Claims 9, 10 and 13 and new claims 60-63 depend from claim 1 and thus cannot be independent. Distinct means related but capable of separate use. Applicants are unclear on how claims 9, 10, and 13 can be used separately from claim 1 because claim 1 must be performed when the methods of these claims are performed. Finally, there can be no undue burden on the Examiner if claim 1 is found to be patentable over the art. Applicants request the Examiner withdraw the restriction requirement with respect to Groups VI, VII, and XV. The traversal is basically for the same reasons as in the above method of claim 1. It is further traversed that since the claims of Groups II-IV, VI-VII, and XV all pertain to methods of identifying or selecting a target-binding protein, it would appear that, contrary to the Examiner's view, they do not have a separate status in the art. This is not found persuasive because the claims of Groups I-IV are distinct. While there are common

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steps in claim 1 and some dependent claims however, the

dependent claims contain additional steps/components.

Accordingly, to search each different elements in each of the

groups would entail a burdensome examination. The traversal

recites only the difference in the preamble and ignores the

differences and/or distinct method steps/components of the body.

As stated in the prior Office action, these claims have acquired

separate status in the art because of the recognized divergent

subject matter containing different steps and/or components.

However, upon applicants' request Group V, claim 14, a linking

claim, would be rejoined with Group I.

The requirement is still deemed proper and is therefore made FINAL.

In the telephonic interview with Ramon Tabtiang on 1/18/05, applicants were informed that an election of species for a target molecule is required. Applicants elected Integrin for the target molecule.

Claims 9-10, 15-40, 45-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement. [Newly added claims 60-63 have been

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withdrawn from consideration since these claims are drawn to the non-elected invention, e.g., claim 17.]

Status of Claims

Claims 1-40 and 45-63 are pending

Claims 9-10, 15-40, 45-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-8 and 11-14 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yousif et al (APMIS).

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Yousif at page 891, col. 2, Materials and Methods describes a method of identifying a protein that binds to a target and to human serum albumin comprising contacting a plurality of diverse proteins such as Nptase, protein A, histone f3, avidin and lysozyme with antibodies (Ig) and Human serum albumin (page 893, paragraph bridging col. 1 and col. 2 up to page 894, col. 1.) and then determining the proteins that bind to the Ig and human serum albumin. See further page 895, paragraph bridging col. 1 and 2 up to page 896, col.2. Accordingly, the specific process steps of Yousif using specific components therein fully meet the broad claimed method steps using components of broad of no define structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yousif et al in view of Sato et al (Biotechnol. Prog.) and Burger et al (Int. J. Cancer).

Yousif is discussed above. Yousif does not disclose a phage display of the proteins (claims 3-4), the in vivo half life of the identified member(as recited in claim 2), invariant cys residues (claim 13). However, Sato discloses at page 182, col.1 the numerous desirable properties of phage display in identifying protein binding target (i.e., ligand). For example, phage display allows one to rapidly screen several billion peptide sequences against a protein target and binders can be selected iteratively and the other disclosed desirable properties. See page 185 as to the amino acid sequences of the peptide being less than 30 and a cyclic peptide.. Also, page 185, RESULTS and DISCUSSION section as to the advantage of cyclic peptide over linear peptide. Burger discloses at page 718 the in vivo half-life determination of a compound containing human serum albumin. Its determination will show whether a compound is rapidly and efficiently cleared from a body of a patient. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the conventional method of Yousif with phage display as taught by Sato for the advantages derived from said phage display. The

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numerous advantages provided by phage display would motivate one to its use. Also, to determine the half-life of the identified target binding proteins of Yousif would have been obvious as taught by Burger. The motivation is to determine how rapidly or efficiently a compound is cleared from the system.

Claims 1-8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yousif et al in view of Sato et al (Biotechnol. Prog.) and Burger et al (Int. J. Cancer) and further in view of Rouslahti. [This rejection is based on the elected target species, integrin].

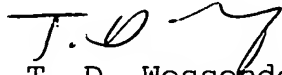
Yousif does not disclose the target as integrin. However, Rouslahti discloses at col. 1, lines 25-33 that integrins control many medically important biological phenomena, such as cell migration in development, tissue repair, cancer cell differentiation, platelet aggregation and homing of immune system cells and neuronal processes. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use integrin as a target in the method of Yousif as taught by Rouslahti. One would have been motivated to determine integrin as a target because of its numerous effects or medical biological phenomena, specifically its effect on cancer cells.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

January 24, 2005